REMARKS

Applicant's attorney notes with appreciation the particularly thorough search and the Examiner's application of the cited art to the claims previously presented. With this Response, applicant amends claims 1 and 14 to more clearly recite and better protect the invention. As so amended, the claims are believe to be clearly allowable of the art of record. Claim 21 is amended to recite the feature described at page 28, end of the first paragraph, thus removing the indefiniteness noted by the Examiner.

By way of overview, applicant's invention employs many techniques and elements of microbiological screening or testing that have been used or proposed for clinical, epidemiological or other public health purposes. However, unlike the art addressing food-borne diseases or pathogens, applicant's invention does not seek to reduce the labor involved in the epidemiological screening of target populations after the outbreak of an illness, or to test for toxins in already processed, warehoused or shipped food products, or to simply screen for pathogens. Applicant's probes and method of testing preferably include at least some assays for pathogens, and this factor is perhaps suggestive of the prior art. However, as now more clearly enunciated in the amended claims, applicant's method and probes are intended for prospective application to material that is to be, or is being, processed into a food product, and it employs a spectrum of target species that may be present in the sample, *wherein the target species include species affecting quality or processing of the food product,* and it produces a distribution *such that the distribution enables effective adjustment* of the processing. Thus, the invention requires a special, food-processing-related palette of organisms, and performs prospective or contemporaneous testing to affect the process.

Moreover, another claimed distinction is that the claimed invention produces a *distribution*. Unlike the "distribution" of the cited Megerle reference (which refers to the detection of an organism's presence and the *geographical location on the surface of the earth*

where it was detected, applicant's "distribution" may be aptly called a *species spectrum*. It represents the types (and preferably concentrations) of organisms present. This distribution itself forms a piece of information; it may serve to characterize, to a trained naturalist/biologist, the ecological niche where the food component originated. It may also serve to characterize or identify, to a food-processing expert, particular food-industry concerns such as taste, texture, that may be addressed by known techniques if caught in time; or it may provide an indicator calling for the need to test for a rare contaminant. Neither this added information, nor the notion of contemporaneous testing of a food product sample to form a distribution appears in the art of record.

Moreover, the notion of forming a database of food product microbiology distributions is also believed to be new. Applicant's invention is singularly informative. The food product oriented distribution, like a spectrograph, intrinsically contains information that if compiled and correlated with external events (source, weather, supplier, historical recall notices) can be relied on as a test for the external occurrence.

Thus, the application of multispecies array testing to unprocessed foodstuff components in a food processing line, and the use of multispecies distributions to characterize and control food processing, amounts to a conceptually quite different method than the after-the-fact screening of populations or finished products to determine what went wrong or where. The characterization of a component or ingredient foodstuff by determining the *distribution* of a spectrum of microbiological species (e.g., bacteria or fungi) present in the foodstuff, and further steps of responding to the distribution with *process* steps such as adjusting temperature, pH, flavoring or composition of a food product in preparation, or taking business operation steps, such as identifying harvest conditions, geographic source and other factors for sorting or choosing component foodstuffs, are all patentable.

Thus, while pathogenic organisms are important, and are preferably included in the testing pallette, the various microbiological testing steps are being applied, not simply to screen

and identify a pathogen, but to determine a distribution that represents information about the foodstuff. By contrast, the mentions of such testing in the cited art are believed to be applied to clinical samples or processed products, and aimed at after-the-fact epidemiological pinpointing of source of a pathogen or cause of an outbreak, rather than characterizing of a foodstuff or adjusting its processing parameters. The closest art, involving water sampling to expedite required assays for pathogens has no relation to food processing.

For all of the above reasons, applicant respectfully requests that the Examiner reconsider the application and allow all claims at this time.

In the event that the Examiner considers that any other matter requires attention before allowance, the Examiner is urged to telephone the responsible attorney to address such matter or schedule an interview so as to expedite further prosecution of the application. Please note that the below-signed attorney will be leaving this law firm shortly, and **future correspondence and telephone calls should be directed to attorney William C. Geary at 617 439-2766 at the firm address below.**

Respectfully submitted,

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MARKED UP COPY SHOWING CLAIM AMENDMENTS

1.(Twice Amended) A method of food product testing, such method including the steps of

taking a sample of a food product [and preparing the sample] , the sample including at least one unprocessed foodstuff for preparation of the food product, and preparing the food sample for assay of genomic material [from] of a plurality of target species potentially present in the food product, and

contacting the prepared food sample with an array of probes directed to multiple regions of genomic material for each of a plurality of said target species

such that said material hybridizes at loci of said array, to simultaneously detect genomic material from a plurality of said target species, and

forming an output distribution representative of the target species that are present in the food sample , wherein the target species include species affecting quality or processing of the food product such that the distribution enables effective adjustment of said processing.

2. (Once Amended) The method of claim 1, wherein the step of preparing includes the step of culturing the food sample to increase populations of a plurality of the target species prior to testing with the array of probes.

3. The method of claim 2, wherein the step of preparing includes the steps of
extracting nucleic acid from target organisms, and
labeling and amplification of gene regions prior to detection with the probe array.

4. The method of claim 3, wherein the step of labeling is performed after the step of amplification.

5. The method of claim 3, wherein the step of amplification is performed by automated fluidics and incubation to produce output material for detection by said array.

6. The method of claim 1, carried out by an automated sample preparation and array testing system.

7. (Once Amended) The method of claim 6, further wherein a computer operates upon an output of an array reader to output said distribution, and including the steps of storing an output distribution in a database together with data regarding the food sample from which the distribution is derived, and operating a data mining program effective to correlate a detected distribution with stored database information.

8. (Once Amended) The method of claim 1, wherein the step of preparing the sample includes the steps of recovering a plurality of different microorganisms from the food sample, extracting DNA from the plural different microorganisms, and simultaneously amplifying plural target sequences present in the recovered DNA for each of said different microorganisms.

9. (Once Amended) The method of claim 1, further comprising the step of correlating the output distribution with a database wherein the database includes data of at least one type selected from among

(i) other output distributions,

(ii) parameters related to the source, condition or processing of food in the sample from which the ouput distribution was taken, and

(iii) parameters related to the source, condition or processing of food in the sample from which other ouput distributions were taken.

10. CANCELED

11. CANCELED

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14.(Twice Amended) A testing method comprising the steps of

preparing an array having plurality of probes directed to target sequences of each of a defined plurality of different target species wherein the target species include species affecting quality or processing of a food product

preparing a sample of the food product, wherein the step of preparing a sample includes extracting DNA from the sample, including sequences of the species present in the sample,.

treating the extracted DNA with a PCR protocol effective to preferentially and simultaneously increase the level of target DNA sequences of the defined plurality of different target species, and

hybridizing the amplified DNA to the probes on the array and forming an output distribution representative of the target species present in the sample such that the distribution enables effective adjustment of said processing.

15. The testing method of claim 14, further comprising the steps of storing the output distribution in a database.

16. The testing method of claim 15, further comprising the step of mining the database to determine a correlation of species with an extrinsic parameter.

17. The testing method of claim 14, wherein the species are foodborne species affecting food safety or quality.

18. (Once Amended) The testing method of claim 14, wherein the target sequences include species sequences coding for factors involved in pathogenesis or virulence factors.

19. The testing method of claim 14, wherein the target sequences are species sequences selected for efficient PCR amplification as a group.

20. The testing method of claim 14, wherein the array tests for a pallette of species selected from among product colonizing species, environment colonizing species, and mammalian colonizing species.

21. (Once Amended) The testing method of claim 16, further comprising the step of displaying the distribution with a note [indicating required action] describing adverse consequences or process warning indications associated with the detected distribution.

22. CANCELED

23. The testing method of claim 14, wherein the target sequences are species sequences selected for efficient probe hybridization and detection as a group.

24. The testing method of claim 14, further including the steps of determining sensitivity and cross reactivity of the array.

25. The testing method of claim 14, wherein the output distribution indicates amount of each target species present in the sample.